REMARKS

FORMAL MATTERS

In the Final Office Action, the Examiner indicated that claims 27-28, 32-33, 38-39, 43-44, 46-64, and 65-69 are pending; however, the highest number claims submitted was 68. All of the claims have been rejected.

WRITTEN DESCRIPTION REJECTION

The Examiner has rejected all of the pending claims under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description support in the specification. The Examiner indicates that the instant invention is drawn to polypeptide fragments of viral proteins, specifically viral Env proteins, and alleges that the claimed polypeptides are described based on the method of obtaining the sequences of yet undiscovered and undisclosed polynucleotide sequences.

Applicants previously argued that the claimed proteins all share conserved sequences. Applicants have also argued that a product-by-process claim has written description support in the specification when the claimed process has actually been used to produce the product. Finally, Applicants argued that the specification identified a representative number of species to support the genus.

In response, the Examiner asserts that while the application contains written description support for the oligonucleotide primers used in the process and the method of preparing a polypeptide using the primers, it does not have support for additional allegedly undisclosed polypeptides. Specifically, the Examiner asserts that

polypeptides cannot be described by a portion of their sequence as changes in protein sequence can affect the activity of a protein.

The U.S.P.T.O. Written Description Guidelines state that written description can be met by:

> Show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

Guidelines, 66 Fed. Reg. at 1106.

The Written Description Guidelines establish that a partial structure can constitute a sufficient identifying characteristics to provide written description support for the claimed invention. The discussion of protein activity is misplaced as the claims are directed to polypeptides encoded by the viral genome of an HIV-1, HIV-2, or SIV virus. As the claimed proteins are actually viral proteins necessary for viral function, and are derived from HIV-1, HIV-2, or SIV viruses, the viruses themselves will select for only functional variants of these proteins. Inactive variants would jeopardize viral function, and thus, the variants isolated from functional viral strains will all retain activity.

Additionally, the Office appears to state that a product-by-process claim is only appropriate if it "results in the production of a defined compound." The Office argues that the claimed sequences do not meet that test. No authority for this proposition has been provided. In contrast, Applicants believe that product-by-process claims are well suited for subject matter that does not easily lend itself to physical description. *In re Brown*, 173 U.S.P.Q. 685, 688 (C.C.P.A. 1972) acknowledges that "the lack of physical

description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established.

These claims, unlike the Office assertion, were "developed in response to the need to enable an applicant to claim an otherwise patentable product that resists definition by other than the process by which it is made." *In re Thorpe*, 227 U.S.P.Q. 964, 965-66 (Fed. Cir. 1985). If all products could be described as "defined compounds," there would be no need for product-by-process claims. Therefore, it is appropriate to describe products that resist conventional definitions by the processes used to make them, as Applicants have done here.

Applicants point out that dependent claims 49-64 recite the particular viral strain that the polypeptides are derived from. On page 2 of the Office Action, the Examiner concedes that the inventors were in possession of the claimed sequences disclosed drawn to the specific viral strains disclosed in the specification HIV-1 Mal, HIV-1 Eli, HIV-1 Bru, HIV-2 Rod (CNCM No. I-522), and SIV-1 MAC (CNCM No. I-521). Applicants submit that these claims obviate the rejection.

Therefore, Applicants request that this rejection be withdrawn.

ENABLEMENT REJECTION

The Examiner has also rejected all of the pending claims under 35 U.S.C. § 112, first paragraph, as allegedly not enabled by the specification. The Examiner concludes that, while the specification provides a method of screening for nucleotide sequences

that encode proteins, the specification does not disclose the structure of the proteins belonging to viral strains and mutants other than the five particular ones disclosed in the specification.

Applicants have previously argued that the specification provides detailed reaction conditions for the claimed process, information on starting materials, and examples of polypeptides isolated using this process. These arguments focused on the requirement that the skilled artisan must be able to make the polypeptides in order to enable the claimed invention.

In this Office Action, the rejection now focuses on whether the specification enables the skilled artisan to use the polypeptides. The Examiner alleges that changes in sequence can alter a protein's activity. To support this argument, the Examiner has cited a collection articles showing that point mutations in various proteins can affect the activity of those proteins.

This line of argument fails to account for the fact that the claimed polypeptide fragments are characterized as being encoded by a nucleotide sequence from a viral genome selected from the group consisting of HIV-1, HIV-2, and SIV, which are expressed by the claimed method. As discussed above, the claimed invention is directed only to polypeptides that are encoded by nucleotide sequences isolated from actual viruses. The virus itself selects for proteins with the activity required to fulfill its role in viral propagation. Only functional forms of these key viral proteins will allow for viral survival. Therefore, only active forms of the proteins will be isolated using the recited process method.

CONCLUSION

In view of the foregoing remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

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Respectfully submitted,

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Dated: February 22, 2005

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